

In response to the Notice of Non-Compliant Amendment of October 31, 2003, copy enclosed, Applicant submits the entire "Amendment to the Claims" section of Applicants' Amendment document.

IN THE CLAIMS

1. (Currently Amended) A stable pharmaceutical composition containing a therapeutically effective amount of a [small or medium size] peptide or of a pharmaceutically acceptable derivative thereof selected from the group consisting of derivatives and analogues of oxytocin and vasopressin and the salts thereof and further containing a buffer in aqueous solution, wherein it is free from [preservatives] adsorption inhibitors preventing adsorption of the active principle onto container walls and free from antioxidants and antimicrobial additives.
2. (Currently Amended) A stable pharmaceutical composition consisting of a therapeutically effective amount of a [small or medium size] peptide or of a pharmaceutically acceptable derivative thereof selected from the group consisting of derivatives and analogues of oxytocin and vasopressin and the salts thereof and of a buffer in aqueous solution.

Claims 3-9 (CANCELLED)

10. (Currently Amended) A The Sstable pharmaceutical composition according to claim [9] 1, wherein the peptide is selected from the group consisting of the analogues of vasopressin, and the salts thereof.
11. (Currently Amended) The Sstable pharmaceutical composition according to claim [3] 1, wherein the analogue of vasopressin contains a mercaptopropanoyl radical.

12. (Currently Amended) The stable pharmaceutical composition according to claim [5] 1, wherein the analogue of vasopressin is desmopressin acetate hydrate.

13. (Currently Amended) The stable pharmaceutical composition according to claim 1 or 2, having a pH comprised between 3.5 and 6.

14. (Currently Amended) The stable pharmaceutical composition according to claim 1, [containing a] wherein the buffer is selected from the group consisting of citric acid/disodium phosphate dihydrate and citric acid/trisodium citrate dihydrate.

15. (Currently Amended) The stable pharmaceutical composition according to claim 2, [further containing a] wherein the buffer is selected from the group consisting of citric acid/disodium phosphate dihydrate and citric acid/trisodium citrate dihydrate.

16. (Currently Amended) The stable pharmaceutical composition according to claim 1, containing an agent for controlling the osmolarity.

17. (Currently Amended) The stable pharmaceutical composition according to claim 2, further containing an agent for controlling the osmolarity.

18. (Currently Amended) The stable pharmaceutical composition according to claim [16] 12, wherein the agent for controlling the osmolarity is sodium chloride.

19. (Currently Amended) The stable pharmaceutical composition according to claim 1, containing at least 0.02 mg of desmopressin, at least 3 mg of [a] the buffer, and an amount of an agent for controlling the osmolarity such that the osmolarity is kept at the physiologic values of the human plasma, and 1 ml of purified water.

20. (Currently Amended) The stable pharmaceutical composition according to claim 2, containing at least 0.02 mg of desmopressin, and containing at least 3 mg of [a] the buffer, and further containing an amount of an agent for controlling the osmolarity

such that the osmolarity is kept at the physiologic values of the human plasma, in 1 ml of purified water.

21. (Currently Amended) The sstable pharmaceutical composition according to claim [19] 15, containing from 3 to 6 mg of citric acid/disodium phosphate dihydrate buffer, or from 5 to 11 mg of citric acid/trisodium citrate dihydrate buffer.
22. (Currently Amended) The Sstable pharmaceutical composition according to claim [19] 15, containing from 0.02 to 0.15 mg of desmopressin, from 1 to 2.5 mg of citric acid monohydrate, from 2 to 5 mg of disodium phosphate dihydrate, 1 ml of water and an amount of sodium chloride such that the osmolarity is kept at the physiologic values of the human plasma.
23. Currently Amended) The Sstable pharmaceutical composition according to claim [22] 18, containing 0.1 mg of desmopressin, 1.7 mg of citric acid monohydrate, 3 mg of disodium phosphate dihydrate, 1 ml of water and an amount of sodium chloride such that the osmolarity is kept at the physiologic values of the human plasma.
24. (Currently Amended) The Sstable pharmaceutical composition according to claim [2] 22, containing 0.1 mg of desmopressin, and [further] containing 1.7 mg of citric acid monohydrate, 3 mg of disodium phosphate dihydrate, in 1 ml of water and further an amount of sodium chloride such that the osmolarity is kept at the physiologic values of the human plasma.
25. (Withdrawn) Process for preparing the pharmaceutical composition according to claim 1, comprising operating in pre-sterile environment, steriley filtrating through 0,22 µm filters, collecting the filtrate in sterile environment and distributing it in sterile vials.

26. (Withdrawn) Process for preparing the pharmaceutical composition according to claim 2, operating in pre-sterile environment, steriley filtrating through 0,22 µm filters, collecting the filtrate in sterile environment and distributing it in sterile vials.

27. (Withdrawn) Spray unit containing a composition according to claim 1, 5 and equipped with a multidose pump, absolute filter for the aspiration air, and an auto-blocking mechanism of the actuator.

28. (Withdrawn) Spray unit containing a composition according to claim 2, and equipped with a multidose pump, absolute filter for the aspiration air, and an auto-blocking mechanism of the actuator.

10 29. (Withdrawn) Spray unit according to claim 27, wherein the vial is of glass.

30. (Withdrawn) Spray unit according to claim 27, wherein the vial is of plastic.

31. (New) The stable pharmaceutical composition according to claim 2, wherein the peptide is selected from the group consisting of the analogues of vasopressin, and the salts thereof.

32. (New) The stable pharmaceutical composition according to claim 4, wherein the analogue of vasopressin contains a mercaptopropanoyl radical.

33. (New) The stable pharmaceutical composition according to claim 6, wherein the analogue of vasopressin is desmopressin acetate hydrate.

34. (New) A stable pharmaceutical composition according to claim 16, containing from 3 to 6 mg. of citric acid/disodium phosphate dihydrate buffer, or from 5 to 11 mg. of citric acid/trisodium citrate dihydrate buffer.

35. (New) A stable pharmaceutical composition according to claim 16, containing from 0.02 to 0.15 mg of desmopressin, from 1 to 2.5 mg., of citric acid monohydrate from 2 to 5 mg of disodium phosphate dihydrate, 1 ml of water and further an amount of sodium chloride such that the osmolarity is kept at the physiologic values of the human plasma.

36. (New) The stable pharmaceutical composition according to claim 2 having a pH comprised between 3.5 and 6.

37. (New) The stable pharmaceutical composition according to claim 13 wherein the agent for controlling the osmolarity is sodium chloride.